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# SENATE BILL No. 206

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## DIGEST OF INTRODUCED BILL

**Citations Affected:** IC 25-26-21.

**Synopsis:** Home medical equipment services provider licensing. Requires a home medical equipment services provider to be licensed by the board of pharmacy. Authorizes the board to conduct inspections, issue licenses, discipline providers for violations, and adopt rules to: (1) specify the equipment to be regulated; (2) set standards for the licensure of services providers; (3) govern the safety and quality of services that are provided; (4) recognize certain accredited individuals for purposes of issuing a temporary license; and (5) set reasonable fees for the application, issuance, and renewal of a license.

**Effective:** July 1, 2005.

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January 4, 2005, read first time and referred to Committee on Health and Provider Services.

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First Regular Session 114th General Assembly (2005)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2004 Regular Session of the General Assembly.

## SENATE BILL No. 206

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

*Be it enacted by the General Assembly of the State of Indiana:*

- 1       SECTION 1. IC 25-26-21 IS ADDED TO THE INDIANA CODE  
2       AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE  
3       JULY 1, 2005]:  
4       **Chapter 21. Home Medical Equipment Services Providers**  
5       **Sec. 1. As used in this chapter, "board" refers to the Indiana**  
6       **board of pharmacy established by IC 25-26-13-3.**  
7       **Sec. 2. As used in this chapter, "home medical equipment"**  
8       **means technologically sophisticated medical devices that may be**  
9       **used in a residence, including the following:**  
10       (1) Oxygen and oxygen delivery systems.  
11       (2) Ventilators.  
12       (3) Respiratory disease management devices.  
13       (4) Continuous positive airway pressure (CPAP) devices.  
14       (5) Electronic and computerized wheelchairs and seating  
15       systems.  
16       (6) Apnea monitors.  
17       (7) Transcutaneous electrical nerve stimulator (TENS) units.



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- (8) Low air loss cutaneous pressure management devices.
- (9) Sequential compression devices.
- (10) Feeding pumps.
- (11) Home phototherapy devices.
- (12) Infusion delivery devices.
- (13) Distribution of medical gases to end users for human consumption.
- (14) Hospital beds.
- (15) Nebulizers.
- (16) Other similar equipment determined by the board in rules adopted under section 7 of this chapter.

Sec. 3. As used in this chapter, "home medical equipment services" means the:

- (1) sale;
- (2) rental;
- (3) delivery;
- (4) installation;
- (5) maintenance or replacement; or
- (6) instruction in the use;

of medical equipment used by an individual that allows the individual to reside in a noninstitutional environment.

Sec. 4. As used in this chapter, "provider" means a person engaged in the business of providing home medical equipment services to an unrelated individual in the individual's residence.

Sec. 5. (a) This chapter does not apply to the following:

- (1) A home health agency (as defined in IC 16-27-1-2) that does not sell, lease, or rent home medical equipment.
- (2) A hospital licensed under IC 16-21-2 that:
  - (A) provides home medical equipment services only as an integral part of patient care; and
  - (B) does not provide home medical equipment services through a separate business entity.
- (3) A manufacturer or wholesale distributor that does not sell, lease, or rent home medical equipment directly to a consumer.
- (4) Except as provided under subsection (b), a practitioner (as defined in IC 25-1-11-2) who does not sell, lease, or rent home medical equipment.
- (5) A veterinarian licensed under IC 15-5-1.1.
- (6) A hospice program (as defined in IC 16-25-1.1-4) that does not sell, lease, or rent home medical equipment.
- (7) A health facility licensed under IC 16-28 that does not sell, lease, or rent home medical equipment.

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(b) A pharmacist licensed in Indiana or a pharmacy that sells, leases, or rents home medical equipment:

(1) is not required to obtain a license under this chapter;

(2) is subject to the:

(A) requirements of this chapter; and

(B) requirements established by the board by rule under this chapter.

**Sec. 6. (a)** A person seeking to provide home medical equipment services in Indiana shall apply to the board for a license in the manner prescribed by the board.

(b) A provider shall do the following:

(1) Comply with:

(A) federal and state law; and

(B) regulatory requirements;

for home medical equipment services.

(2) Maintain a physical facility and medical equipment inventory in Indiana on a site zoned for commercial use.

(3) Purchase and maintain in an amount determined by the board:

(A) product liability insurance; and

(B) professional liability insurance;

and maintain proof of the insurance coverage.

(4) Establish procedures to ensure that personnel engaged in the following home medical equipment activities receive annual continuing education established by the board:

(A) Delivery.

(B) Orientation of a patient in the use of home medical equipment.

(C) Reimbursement assistance.

(D) Maintenance.

(E) Repair.

(F) Cleaning and inventory control.

(G) Administration of home medical equipment services.

(5) Maintain clinical records on a customer receiving home medical equipment services.

(6) Establish home medical equipment maintenance and personnel policies.

(7) Provide home medical equipment emergency maintenance services available twenty-four (24) hours a day.

(8) Comply with the rules adopted by the board under this chapter.

**Sec. 7. (a)** The board may adopt rules under IC 4-22-2 to do the

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following:

(1) Specify home medical equipment in addition to the home medical equipment set forth in section 2 of this chapter that is to be regulated under this chapter.

(2) Set standards for the licensure of providers.

(3) Govern the safety and quality of home medical equipment services that are provided to customers.

(4) Recognize accreditation organizations under section 9 of this chapter.

(5) Specify the amount of insurance coverage required under section 6(b)(3) of this chapter.

(6) Set reasonable fees for the application, issuance, and renewal of a license under this chapter and set other fees permitted under IC 25-1-8.

(b) The board may consult with individuals engaged in the home medical equipment services business to advise the board on the formulation of rules under subsection (a). The individuals may not be compensated or reimbursed for mileage by the board.

Sec. 8. (a) Except as provided in section 9 of this chapter, a provider must be licensed by the board before the provider may provide home medical equipment services. If a provider provides home medical equipment services from more than one (1) location in Indiana, the provider must obtain a license under this chapter for each location.

(b) An applicant shall submit the application to the board on a form adopted by the board. The nonrefundable application fee set by the board must be submitted with the application. The fee may be used to cover the board's costs of reviewing and inspecting applications and issuing a license under this chapter.

(c) If the board determines that the applicant:

(1) meets the standards set forth by the board; and

(2) has satisfied the requirements under this chapter and the requirements established by the board by rule;

the board shall notify the applicant in writing that the license is being issued to the applicant. The license is effective on the applicant's receipt of the written notification.

(d) A license issued under this chapter is effective for not more than two (2) years, beginning on a date determined by the board.

(e) The board may renew a license every two (2) years.

Sec. 9. (a) An applicant for a license under this chapter may submit documents that show the applicant's accreditation through a national organization recognized by the board.

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(b) The board shall issue a temporary license to an applicant under subsection (a) when the board:

(1) receives a copy of a valid accreditation letter from a national organization that the board has recognized by rule under section 7(a)(4) of this chapter; and

(2) has conducted an inspection under section 10 of this chapter in which the inspector determines that the applicant meets the inspection requirements.

Sec. 10. (a) The board may inspect the operations and facilities of an applicant for a license under this chapter to determine whether to issue the applicant a license.

(b) The board may conduct random inspections at any time for the following reasons:

(1) To ensure the integrity and effectiveness of the licensing process.

(2) To investigate a consumer complaint or a complaint by a qualified source as identified by the board.

(c) The board shall send the provider a report of the board's findings after the board completes an investigation under this section.

(d) A provider that disputes the report in subsection (c) may file an appeal with the board not later than thirty (30) days after receipt of the report. The board shall review the inspection report and, upon the provider's requests, conduct a new inspection.

(e) The board shall employ qualified inspectors to investigate complaints and conduct inspections. Investigators may review and audit records under an investigation or inspection during the inspected facility's normal business hours at the place of business of the provider being investigated.

(f) The board and the board's employees may not disclose confidential information obtained during an investigation except:

(1) during a disciplinary hearing held under section 11 of this chapter; or

(2) under a court order.

Sec. 11. The board may discipline the holder of a license under IC 25-1-9 after a hearing or for any of the following reasons:

(1) Violation of this chapter or violation of a rule established by the board.

(2) Violation of a board order.

(3) Failure to meet the standards set forth in section 6(b) of this chapter.

(4) The conviction or plea of guilty for a felony or

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1       misdemeanor that:

2           (A) involves dishonesty; or

3           (B) is directly related to providing home medical  
4           equipment services.

5       (5) Negligence or gross misconduct in providing home medical  
6       equipment services.

7       (6) The aid, assistance, or willful allowance of another person  
8       in violating a provision under this chapter or a rule adopted  
9       by the board.

10      (7) Failure to provide within sixty (60) days information in  
11      response to a written request from the board.

12      (8) The engagement in conduct that is likely to deceive,  
13      defraud, or harm the public.

14      (9) Denial, revocation, suspension, or restriction of a license  
15      in another state or jurisdiction to provide home medical  
16      equipment services for a reason other than the failure to  
17      renew the license.

18      (10) The receipt of a fee, commission, rebate, or other form of  
19      compensation for services not rendered.

20      (11) Knowingly making or filing false records, reports, or  
21      billings in the course of providing home medical equipment  
22      services, including false records, reports, or billings prepared  
23      for or submitted to state or federal agencies or departments.

24      (12) Failure to comply with federal rules issued under the  
25      federal Medicare program (42 U.S.C. 1395 et seq.) relating to  
26      operations, financial transactions, and general business  
27      practices of home medical equipment services providers.

28      Sec. 12. (a) A person engaging in the business of home medical  
29      equipment services who:

30           (1) is required to be licensed under this chapter; and

31           (2) knowingly provides home medical equipment services  
32           without a license issued under this chapter;

33      commits a Class A misdemeanor.

34           (b) Each day a violation continues constitutes a separate offense.

35           (c) The board may, in the name of the state and through the  
36      attorney general, apply in a court to enjoin a person from  
37      providing home medical equipment services in violation of this  
38      chapter.

39      SECTION 2. [EFFECTIVE JULY 1, 2005] (a) As used in this  
40      SECTION, "board" refers to the Indiana board of pharmacy  
41      established by IC 25-26-13-3.

42           (b) As used in this SECTION, "provider" has the meaning set

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1       forth in IC 25-26-21-4, as added by this act.

2       (c) A person engaged in providing home medical equipment  
3       services (as defined in IC 25-26-21-3, as added by this act) business  
4       on June 30, 2005, and through June 30, 2006, is subject to  
5       inspection by the board for compliance with the standards set forth  
6       in IC 25-26-21, as added by this act.

7       (d) If, on the initial inspection under subsection (c), a provider  
8       who is accredited by a national organization passes the inspection,  
9       the board shall issue the provider a license under IC 25-26-21, as  
10      added by this act. If, on the initial inspection under subsection (c),  
11      a provider who is accredited by a national organization does not  
12      meet the inspection requirements, the provider shall be issued a  
13      temporary license for a period of twelve (12) months.

14      (e) When the board issues a temporary license under subsection  
15      (d), the board shall provide the provider in writing a list of the  
16      areas of noncompliance.

17      (f) After the twelve (12) month period described in subsection  
18      (d), the board shall conduct an inspection to determine whether the  
19      provider is in compliance with the standards set forth in  
20      IC 25-26-21, as added by this act. If the board determines that the  
21      provider meets the standards, the board shall issue the provider a  
22      license under IC 25-26-21, as added by this act. If the board  
23      determines that the provider is not in compliance, the board shall  
24      notify the provider in writing that the board is denying the  
25      provider a license.

26      (g) This SECTION expires December 31, 2008.

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